EXHIBIT A

Direct Testimony Declaration of Robert C. Black

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS and 01-CV-339	)	

TRIAL OF CLASS 2 AND 3 CLAIMS

DECLARATION OF ROBERT C. BLACK SUBMITTED AS DIRECT TESTIMONY IN CASE-IN-CHIEF OF ASTRAZENECA PHARMACEUTICALS LP
<u>IN THE TRIAL OF CLASS 2 AND 3 CLAIMS</u>

I, ROBERT C. BLACK, declare as follows:

1. I served as the President of Stuart Pharmaceuticals/ICI Pharma and Zeneca Pharmaceuticals ("Zeneca")—predecessor companies to AstraZeneca Pharmaceuticals LP ("AstraZeneca" or the "Company")—from 1991 to 1999.[1] In 1999, upon the merger of Zeneca Group PLC and Astra AB, I retired from my position with the Company. I have not performed any work for the Company since my retirement.

2. I worked for AstraZeneca for approximately 34 years, in a variety of roles. I started with the Company in 1965, as a sales representative for what was then Stuart Pharmaceuticals. Over the next twenty years, I held a variety of sales-related positions until the mid-1980s when I joined the Planning Department, a group that prepared products for launch.

[1] For sake of clarity, except where otherwise noted, I refer to all of AstraZeneca Pharmaceuticals LP and all predecessor companies as simply "AstraZeneca" or the "Company."

One of the responsibilities of this group was to recommend the launch price for new products, in connection with our department's provision of commercial input into the development process. I then was appointed Director of Marketing and subsequently Vice President of Sales and Marketing, and in 1988 was secunded to the United Kingdom where I functioned as General Manager, Territorial, responsible for all country operations except for the United States. Approximately two years later, I returned to the United States and reassumed the position of Vice President of Sales and Marketing and, in 1991, became President of the Company.

3. As President, my major areas of responsibility included Operations (manufacturing), Human Resources, Finance, Information Technology, Legal, Public Affairs, Business Development, and Sales and Marketing. Zoladex was an important product, but was not among the largest volume products in our line.

Corporate History

4. As President of Zeneca, it was my goal to position the Company to successfully compete as a profit-making enterprise in the U.S. marketplace by developing, manufacturing, and marketing innovative products that improve patients' health. We attempted to do this by, among other things, pricing our products in a manner that balanced patient access with the need to fund research and development of new products.

5. For instance, starting in or around January of 1992, the Company initiated a policy of limiting U.S. price increases (as a total product portfolio) to no greater than the general rate of inflation in the U.S. economy, i.e., the Consumer Price Index ("CPI"). We priced our products in accordance with this policy for a number of years.

6. Zeneca was also committed to providing patients with access to all of its drug treatments. An example of the Company's commitment to making pharmaceutical products widely accessible is the Patient Assistance Program ("PAP"), which was administered by the Zeneca Pharmaceuticals Foundation (the "Foundation"), dating back to 1978. The Foundation provided the Company's products to economically disadvantaged patients, free of charge. By the late 1990s, approximately 35,000 active patients were receiving Zeneca products through the PAP. One of the products that was covered through the PAP was Zoladex. Provision of products through the PAP is a permissible means of providing goods free of charge.

7. At the same time, products like Zoladex needed to provide enough revenue for the Company to recoup the expense of research and development, manufacturing/distribution and selling, general, and administrative costs, and fund the research and development that would sustain future innovation. Zoladex, for instance, was very costly to develop, as it involved decades of research and a complicated manufacturing process, as is discussed more fully below.

Zoladex History

8. Zoladex, which is an injectable, physician-administered drug, was launched in the United States in early 1990 just prior to my return from the United Kingdom.

9. At the time Zoladex was launched, there was only one other luteinizing hormone-releasing hormone ("LHRH") agonist available for the treatment of prostate cancer—Lupron, a drug manufactured by Takeda Abbott Pharmaceuticals ("TAP"). Other than Zoladex and Lupron, treatment for advanced prostate cancer then was limited to orchiectomy or diethylstilbestrol (DES). Indeed, when Zoladex was launched, orchiectomy was the primary course of treatment for prostate cancer, representing nearly half of monotherapy use in newly

diagnosed advanced prostate cancer patients in 1992. Zoladex was the first injectable drug manufactured by the Company, and required a substantial financial investment to bring it to market.

10. The manufacture of Zoladex was undertaken at the Company's Macclesfield Works in the United Kingdom. In order to manufacture Zoladex depots, the Company built a sterile facility, the first in Zeneca history, to provide the environment necessary for the production of these depots.

11. Further complicating the process was the need to develop a customized delivery system consisting of, among other things, a needle capable of delivering Zoladex, which is inserted subcutaneously in pellet form in order to ensure sustained release of the medicine over time.

Pricing History

12. Throughout my employment with the Company, I was generally knowledgeable about various pricing benchmarks. Indeed, it was back in 1965, as a sales representative dealing with OTC products, when I first learned of the terms "average wholesale price" or "AWP," then commonly known as wholesale list price, and "wholesale acquisition cost" or "WAC." WAC was the price at which we sold the product to the wholesaler. AWP had a simple, mathematical relationship to WAC, representing a 20% or 25% markup over WAC, depending on the product.

Zoladex Pricing

13. Pricing recommendations generally originated from the Product Manager, and were elevated through the Marketing Team.

14. From 1991 until my retirement from the Company, I had final authority to approve price increases. Pricing decisions that I focused on and approved related to the WAC of a product, not the AWP, because the Company's revenue was derived from sales based on WAC, or discounts off WAC, not AWP.

15. It was also my responsibility to approve discounts. As a general matter, I did not want to offer discounts, but, depending on competition in a therapeutic area, sometimes discounting was required in order to compete. The rationale for discounting is that while a decrease in unit price would occur, overall sales volume increases (or decreases less).

16. As I recall, the price of Zoladex (as reflected in the WAC reported to third-party publishers such as First DataBank) did not increase for the first three years the product was on the market. From 1993 to 1995, the price of Zoladex increased by approximately 4% annually, and from 1996 to 1998, we implemented several price increases of approximately 7%. The price of Zoladex did not increase in 1999. The markup from WAC to AWP for Zoladex stayed constant at 25%.

17. When Zoladex was launched, we believed that it was as good as, if not better than, Lupron, because its clinical benefits were supported by strong clinical data. However, because Lupron launched first and was entrenched with 100% of the LHRH market by the time Zoladex was introduced, Zoladex was launched at a lower price than Lupron in order to obtain market share. Indeed, we used marketing materials that stated that Zoladex was more economical than Lupron, had a lower patient co-pay, and was cheaper for the system overall.

The documents marked as AZ Defendant's Exhibits 2131 and 2151 are examples of the type of marketing materials we used that focused on Zoladex's lower cost. Nonetheless, sales of Zoladex in the early 1990s were consistently disappointing, and Lupron continued to dominate the LHRH market.

18. We realized that the Medicare Part B reimbursement system, which reimbursed on the basis of AWP instead of acquisition cost, gave doctors an incentive to prefer TAP's higher price rather than Zeneca's lower cost. I recall learning that physicians were benefiting from a greater "spread" between Lupron's AWP and acquisition cost and, consequently, some would not consider using Zoladex in their practices. This spread was sometimes referred to as the physicians' "return to practice."

19. Consequently, in order to gain parity with TAP, i.e., to get treating physicians to consider using Zoladex for their appropriate patients, we designed a discounting program intended to compete with TAP.

20. To that end, in July 1993, we instituted a small, pilot trial discount program to counter TAP's discounted prices for Lupron on sales to doctors. In 1994, we instituted a national, tiered quantity-based discounting program for doctors, offering small discounts from WAC. This program proved successful. Approximately one year later, we instituted a new discounting program that contained additional quantity-based discount tiers.

21. We subsequently adjusted our discount tiers for both the one-month and the three-month Zoladex depots. Throughout this time period, we were operating defensively against TAP, adding higher levels of discounts for higher quantities of Zoladex purchased in an effort to maintain parity with our competition. Our objective was simple—to level the playing field—and in so doing, we were continually responding to TAP. In the absence of this type of pricing

pressure and competition from TAP, I would not have offered these kinds of discounts on Zoladex.

22. This competitive dynamic is the subject of a number of memoranda written by members of the product and marketing teams, such as Keith Patterson, who, around the mid-1990s was the Product Manager for Zoladex. These memoranda recommend that Zeneca respond to TAP in order to compete in the marketplace by either increasing price and/or discounting Zoladex. Some of these recommendations were followed in some manner, while others were not. Although I would not agree with all of the justifications or arguments set forth by the product team in their efforts to advance these pricing strategies, these memoranda do accurately reflect the competitive pressures faced by the Company in the LHRH market. That is, they generally describe the marketplace in which we were operating and identify the obstacles that we faced in our efforts to gain equal footing with TAP.

23. Generally speaking, during my tenure as President of the Company, one of our goals was to sell Zoladex in a market that was dominated by TAP as a result of the reimbursement system created by the federal government. Throughout this period, we made every effort to compete by diminishing the "return to practice" differential between Zoladex and Lupron, while maintaining our status as the lower cost alternative to the patient, the practice, and the government.

24. If we had not discounted Zoladex, sales and market share growth would have stagnated. As a result, Zeneca would have had to substantially reduce its marketing effort, thereby depriving physicians and patients of a lower cost alternative.

Zoladex Samples

25. During my tenure, the Company always maintained a strict policy against the inappropriate use of samples. As a matter of corporate policy, and as clearly stated in the Company's guidebook for employees marked as AZ Defendant's Exhibit 2103 at AZ0229456, distribution of samples in violation of the Prescription Drug Marketing Act ("PDMA") was expressly forbidden: "**NEVER** use samples to 'buy business' or to barter for other items of value. **NEVER** sell samples for any reason." As a matter of corporate policy, the Company prohibited the distribution of samples of Zoladex to providers for the purpose of billing Medicare for free samples.

26. I have been made aware that AstraZeneca pleaded guilty in 2003 to one count of conspiracy to violate the PDMA through the actions of its employees. I understand that, contrary to company policy, certain of these employees gave free drug samples to physicians around 1993 to 1996, with the expectation that these physicians would seek reimbursement for these samples. This behavior was completely inconsistent with Zeneca's policy governing the proper use of samples in effect at that time.

27. Based on my personal knowledge of certain documents and understanding of the types of documents prepared and maintained by AstraZeneca, all of the documents referenced above[2] were, to the best of my knowledge, prepared in the ordinary course of AstraZeneca's business and were maintained by AstraZeneca in the ordinary course of business. In addition, I signed AZ Defendant's Exhibit 2103 in the ordinary course of business at the Company.

[2] AZ Defendant's Exhibits 2103, 2131, 2151.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on November 9, 2006

Robert C. Black